Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of aerobic training and caffeine consumption on quality of life and life expectancy in overweight men in Gachsaran

Protocol summary

Study aim
The effect of aerobic exercise and caffeine consumption on quality of life and life expectancy of overweight men in Gachsaran

Design
The study population of all overweight men aged 40-60 years in Gachsaran voluntarily participated in the study and randomly divided into 4 research groups.

Settings and conduct
Initially, by announcing a call and announcement at Gachsaran Sports Clubs, Offices and Public Places, all overweight men aged 40 to 60 are invited to participate in the study. The subjects were then randomly divided into four groups of 15, (1) control, (2) caffeine, (3) aerobic exercise, and (4) aerobic exercise + caffeine supplement. Questionnaire of quality of life and life expectancy will be completed by the subjects in pre-test and post-test. Aerobic exercise is also performed for eight weeks three sessions per week and each session for about 25 to 40 minutes with an intensity of 60 to 80 percent of maximum heart rate. Caffeine supplementation groups also consume two capsules daily containing 200 mg of caffeine manufactured by the Al-Hawa Iranian Company, licensed by the Ministry of Health.

Participants/Inclusion and exclusion criteria
Subjects aged 40 to 60 years.BMI>30 Exclusion criteria:Special diseases like hypertension; Smoking; Regular exercises in two last years

Intervention groups
The control group(1) did not exercise for 2 months and did not take silymarin.The aerobic training group (2) trained for eight weeks, three sessions per week and each session for 20-40 minutes with an intensity of 60 to 85% of the stored heart rate.The caffeine group (3) consumes two 200 mg silicone-coated Capsule daily.Aerobic Exercise +caffeine (4) group exercise for 2 months and use caffeine capsule.

Main outcome variables
Quality of life؛ Life expectancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200215046506N2**
Registration date: **2020-03-10, 1398/12/20**
Registration timing: **retrospective**

Last update: **2020-03-10, 1398/12/20**
Update count: **0**

Registration date
2020-03-10, 1398/12/20

Registrant information

Name
Ali Khajehlandi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 74 3233 5910

Email address
a.khajehlandi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-23, 1398/07/01

Expected recruitment end date
2019-11-22, 1398/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of aerobic training and caffeine consumption on quality of life and life expectancy in overweight men in Gachsaran

Public title
The effect of aerobic training and caffeine consumption on quality of life and life expectancy in overweight men

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The lack regular exercise in the last two years The age of the subjects is 40 to 60 years

Exclusion criteria:
A history of heart disease Smoking in the last six months

Age
From **40 years** old to **60 years** old

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomly assign the samples to four groups, Excel software is used as follows: First, a list of participants is compiled and we assign each participant a specific number using the RAW function, then randomly select each participant using the RANDBETWEEN and VLOOKUP functions and assign them to each participant. We assign 4 groups to groups. The first, second, third and fourth subjects were assigned to the control group, aerobic exercise group, caffeine consumption group, and aerobic training + caffeine consumption group, respectively. Others are assigned to groups in the same way.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Islamic Azad University ,Gachsaran Branch

Street address
Daneshjo Blvd.,Gachsaran

City
Gachsaran

Province
Kohgilouyeh-va-Boyrahmad

Postal code
63876-75818

Approval date
2020-01-01, 1398/10/11

Ethics committee reference number
IR.IAU.IAUG.REC.1398.007

Health conditions studied

1

Description of health condition studied
Overweight

ICD-10 code
E66

ICD-10 code description
Overweight and obesity

Primary outcomes

1

Description
Quality of life

Timepoint
Two months after intervention

Method of measurement
World Health Organization Quality of Life Questionnaire

Secondary outcomes

1

Description
Life expectancy

Timepoint
Two months after training

Method of measurement
Schneider Life Expectancy Questionnaire

Intervention groups

1

Description
Intervention group: Three sessions per week and each session lasting about 25 to 40 minutes, the subjects exercising at 65 to 80 percent of their maximum heart rate for 40 minutes for 8 weeks.

Category
Other

2

Description
Intervention group: Eight weeks, daily consumption of two 200 mg capsules containing caffeine manufactured by Alhavi Iran
Category
Other

3

Description
Intervention group: Three sessions per week and each session for about 25 to 40 minutes, subjects with 65-80% of maximal heart rate, 40 minutes plus eight weeks, two daily 200 mg capsules containing caffeine manufactured by Alhavi Iran
Category
Other

4

Description
Control group: Consume capsules containing wheat flour
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Islamic Azad University, Gachcaran Branch
Full name of responsible person
ALI Khajehlandi
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No.12, North Tenth Ave., Valiasr Blvd., Gachsaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Islamic Azad University Gachsaran Branch
Full name of responsible person
Amin Mohammadi
Street address
No.31,Western Eighth Ave., shahed Blvd.,Razmandegan Town
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Grant name
معاونت پژوهشی ، دانشگاه آزاد اسلامی واحد گچساران
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Islamic Azad University Gachsaran Branch
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Islamic Azad University Gachsaran Branch
Full name of responsible person
Ali Khajehlandi
Position
Assistant Professor
Latest degree
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Physical Education and Sport Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available